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| Don W. Bulson, Esq. | | | KIM, CHONG R | |
| Renner, Otto, Boisselle & Sklar, LLP 19th Floor | | | ART UNIT | PAPER NUMBER |
| 1621 Euclid Ave. | | | 2623 | ~ |
| Cleveland, OH 44115 | | | DATE MAILED: 07/20/2004 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | |
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| | 09/662,045 | VILSMEIER ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Charles Kim | 2623 | | | | |
| The MAILING DATE of this communication ap | pears on the cover sheet with the c | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPL THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1. after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a replied of the period for reply is specified above, the maximum statutory period Failure to reply within the set or extended period for reply will, by statut Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | 136(a). In no event, however, may a reply be timely within the statutory minimum of thirty (30) days will apply and will expire SIX (6) MONTHS from the cause the application to become ABANDONE | nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| 1) ⊠ Responsive to communication(s) filed on 18 May 2004. 2a) ⊠ This action is FINAL. 2b) ☐ This action is non-final. 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | |
| 4) Claim(s) 1-6,9-13,18 and 19 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 1-6,9-13,18 and 19 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. | | | | | | |
| Application Papers | | | | | | |
| 9) ☐ The specification is objected to by the Examin 10) ☑ The drawing(s) filed on <u>03 November 2003</u> is Applicant may not request that any objection to the Replacement drawing sheet(s) including the correction of the oath or declaration is objected to by the Examination is objected to by the Examination is objected. | fare: a)⊠ accepted or b)□ object e drawing(s) be held in abeyance. See ction is required if the drawing(s) is ob | e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d). | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08 Paper No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail Do 5) Notice of Informal F 6) Other: | | | | | |

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DETAILED ACTION

Response to Amendment and Arguments

- 1. Applicant's amendment filed on May 18, 2004 has been entered and made of record.
- 2. In view of applicant's amendment, the claim objections are withdrawn.
- 3. In view of applicant's amendment, the 112 first paragraph rejections are withdrawn.
- 4. Applicant's arguments have been fully considered, but they are not deemed to be persuasive for at least the following reasons.

Applicants argue (pages 6-7) that the "rejection is improper because there is no motivation to combine Cosman and Nayar." In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the suggestion/motivation for combining the teachings of Cosman and Nayar would have been to enhance the treatment process by providing the capability of detecting the three-dimensional shape of the object at a higher speed (Nayar, page 218 and 223). Therefore, it would have been obvious to combine Cosman with Nayar to obtain the invention as specified in claim 1.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 9 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Referring to claim 9, the phrase "wherein at least one fixed point, detectable by a navigation system, is selected on the patient body part to assign the location and shape of the mapped three-dimensional body part in said navigation system based on the position of said at least one point as also captured by the camera" in lines 1-5 is not sufficiently supported by the applicant's specification. More specifically, the applicant's specification is non-enabling in regards to how the shape of the patient body part is assigned in the navigation system based on the position of the fixed point captured by the camera. A similar rejection is applicable to claim 19.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-6, 9-13, 18, 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Cosman, U.S. Patent No. 6,006,126 ("Cosman") and the article entitled "Shape from Focus: An Effective Approach for Rough Surfaces" by Nayar et al. ("Nayar").

Referring to claim 1, Cosman discloses a method of detecting the shape of a patient body part to be treated, the method comprising the following steps:

- a. producing a camera image of the patient body part (col. 10, lines 51-56 and figure5)
- b. mapping a three-dimensional shape (contour) of the patient body part (col. 10, lines 59-62).

Cosman fails to explicitly disclose that the three dimensional shape (contour) of the patient body is established by mapping an outline of the patient body part in multiple focusing distances of the camera.

Nayar discloses a method of detecting the shape of an object, the method comprising:

- i. producing a camera image of the object (page 221, section 6 and figure 9a)
- ii. mapping an outline of the object, the outline appearing sharp in the image, in a first plane by means of an analyzer connected to the camera (page 218, section 1.3 and page 222). Nayar explains that focus measures F(x, y, d) are determined for each focal plane di (i=1...M). Nayar further explains that the focal plane (di) where the focus measure becomes maximum (d) is obtained with respect to all coordinate points (x, y), and are used to determine the points on the object surface, thereby resulting in an image of the solid shape object (page 222, section 8 and figure 9b). Note that d(x,y) represents the z-coordinate value (depth) of the

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focal plane that includes a point on the object surface at (x, y). Therefore, all the points on the object surface are determined for each focal plane (di, i=1, 2, ...M). The Examiner notes that determining all the points of the object surface for each focal plane (the points on the object surface having the same d values) is analogous to mapping an outline of the object in each focal plane, since the surface points in each focal plane represent a cross section of the object surface at a particular height (z=d), wherein the cross section is characterized by a plane that includes all the points of the object surface intersecting that plane, thereby forming an outline of the object surface (see figure 9b).

Nayar further discloses:

- iii. altering the focus distance of the camera (page 220, section 4 and page 221, section 6)
- iv. mapping a sharp outline of the object in a second plane by means of an analyzer [page 222, section 8. See also the discussion in regards to (ii) above]
- v. repeating steps ii) to iv) until a sufficient number of outlines has been mapped so that the three-dimensional shape of the object can be established (page 222 and figure 9b).

Cosman and Nayar are both concerned with image processing systems for detecting the three dimensional shape of an object. Nayar provides a fast, efficient, and reliable shape extraction method that is capable of detecting the three-dimensional shape of an object having a variety of different surfaces at a higher speed (Nayar, page 218 and 223). Therefore, it would have been obvious to modify the method of Cosman, so that the three-dimensional shape of the patient body part is determined by mapping an outline of the patient body part in multiple

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focusing distances of the camera, as taught by Nayar. The suggestion/motivation for doing so would have been to reduce processing time and thereby enhance the treatment process.

Referring to claim 2, Nayar further discloses that the differences in contrast are mapped to establish which outline appears sharpened in the image (page 221, section 6).

Referring to claim 3, Cosman discloses that the camera is a video camera (col. 10, lines 59-60), but fails to explicitly disclose that the video camera has a very small depth of sharpness. However, cameras having a very small depth of sharpness were exceedingly well known in the art. For example, Nayar discloses a camera having a very small depth of sharpness (page 221, right column and figure 8. Note that the camera on the microscope will have a very small depth of sharpness). Therefore, it would have been obvious to combine the teachings of Cosman and Nayar, for the reasons stated above (claim 1).

Referring to claim 4, Cosman further discloses that the markers are applied to the object to highlight specific points on the patient body part for identification (col. 5, lines 44-45 and col. 10, lines 64-67).

Referring to claim 5, Nayar further discloses that the analyzer used is a computer including an image processing program, in which digital signals are processed (page 223, section 9).

Referring to claim 6, Cosman further discloses that the camera can be used with a surgical microscope (col. 2, lines 13-20 and figure 4) but fails to explicitly disclose that the camera is used on a surgical microscope. Nayar discloses that the camera is used on a microscope (figure 8). Therefore, it would have been obvious to combine the teachings of Cosman and Nayar, for the reasons stated above (claim 1).

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Referring to claim 9, Cosman further discloses that at least one fixed point, detectable by a navigation system, is selected on the patient body part to assign the location and shape of the mapped three-dimensional body part in said navigation system based on the position of said at least one point as also captured by the camera (col. 5, lines 44-45, col. 10, lines 46-67, and figure 5).

Referring to claim 10, Cosman further discloses that the method is used together with a navigation system for location referencing in surgical operations (col. 2, lines 13-29).

Referring to claim 11, Cosman further discloses that the shape of the patient body part is assigned to a shape determined by a preoperative scan to permit location correction (col. 10, lines 46-67).

Referring to claim 12, Cosman fails to explicitly disclose that the mapped shape of the patient body part is used to automatically focus object planes defined by the user.

Nayar explains that the mapped three dimensional shape of the object is obtained from d(x,y) values, wherein d is the z-coordinate (depth) of the focal plane where the focus measure becomes maximum for all coordinate values (x, y), as noted above. Therefore, the d(x, y) values of the mapped shape of the object in a selected focal plane (di, i=1, 2...M) will represent the points on the object surface that are in focus.

Nayar fails to explicitly disclose that a user defines the plane. Official notice is taken that it was exceedingly well known for users to define a plane in an object image. Therefore, it would have been obvious for a user to define a plane in the object image of Nayar, in order to enhance the flexibility of the system by allowing the user to analyze specific portions of the object image for further processing. Therefore, if the user defines a plane, the mapped shape of

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the object [d(x, y)] can be used to automatically focus the selected plane. It would have been obvious to combine the teachings of Cosman and Nayar, for the reasons stated above (claim 1).

Referring to claim 13, Cosman fails to explicitly disclose that the mapped shape of the patient body part is used to produce an image which is sharp at any depth.

Nayar discloses that the shape of the object is used to produce an image which is sharp at any depth [page 222. Nayar explains that the d(x, y) values are used to display an image of the solid shape object (figure 9b). The Examiner notes that the solid shape image obtained from the d(x, y) values is sharp at any depth, since d is the z-coordinate (depth) where the focus measure becomes maximum for all coordinate values (x, y). It would have been obvious to combine the teachings of Cosman and Nayar, for the reasons stated above (claim 1).

Referring to claim 18, Cosman further discloses processing the mapped threedimensional shape of the patient body part with a navigation system to incorporate the threedimensional shape of the patient body part in navigation (col. 10, lines 59-67 and figure 5).

Referring to claim 19, Cosman discloses a method of detecting the shape of a patient body part to be treated, the method comprising the following steps:

- a. applying at least one marker (508A) to the patient body part, the at least one marker being detectable by a navigation system (col. 10, lines 26-67 and figure 5)
- b. producing a camera image of the patient body part (col. 10, lines 51-56 and figure 5)
- c. mapping a three-dimensional shape (contour) of the patient body part (col. 10, lines 59-62)

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d. assigning a location and shape of the patient body part in the navigation system based on a position of the at least one marker captured by the camera (col. 5, lines 44-45, col. 10, lines 46-67, and figure 5)

e. processing the shape of the patient body part by the navigation system monitoring a treatment zone to incorporate the outer shape of the patient body part in navigation (col. 10, lines 59-67 and figure 5).

Cosman fails to explicitly disclose that the three dimensional shape (contour) of the patient body is established by mapping an outline of the patient body part in multiple focusing distances of the camera.

Nayar discloses a method of detecting the shape of an object, the method comprising:

- i. producing a camera image of the object (page 221, section 6 and figure 9a)
- ii. mapping an outline of the object, the outline appearing sharp in the image, in a first plane by means of an analyzer connected to the camera (page 218, section 1.3 and page 222). Nayar explains that focus measures F(x, y, d) are determined for each focal plane di (i=1...M). Nayar further explains that the focal plane (di) where the focus measure becomes maximum (d) is obtained with respect to all coordinate points (x, y), and are used to determine the points on the object surface, thereby resulting in an image of the solid shape object (page 222, section 8 and figure 9b). Note that d(x,y) represents the z-coordinate value (depth) of the focal plane that includes a point on the object surface at (x, y). Therefore, all the points on the object surface are determined for each focal plane (di, i=1, 2, ...M). The Examiner notes that determining all the points of the object surface for each focal plane (the points on the object surface having the same d values) is analogous to mapping an outline of the object in each focal

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plane, since the surface points in each focal plane represent a cross section of the object surface at a particular height (z=d), wherein the cross section is characterized by a plane that includes all the points of the object surface intersecting that plane, thereby forming an outline of the object surface (see figure 9b).

Nayar further discloses:

- iii. altering the focus distance of the camera (page 220, section 4 and page 221, section 6)
- iv. mapping a sharp outline of the object in a second plane by means of an analyzer [page 222, section 8. See also the discussion in regards to (ii) above]
- v. repeating steps ii) to iv) until a sufficient number of outlines has been mapped so that the three-dimensional shape of the object can be established (page 222 and figure 9b).

Cosman and Nayar are both concerned with image processing systems for detecting the three dimensional shape of an object. Nayar provides a fast, efficient, and reliable shape extraction method that is capable of detecting the three-dimensional shape of an object having a variety of different surfaces at a higher speed (Nayar, page 218 and 223). Therefore, it would have been obvious to modify the method of Cosman, so that the three-dimensional shape of the patient body part is determined by mapping an outline of the patient body part in multiple focusing distances of the camera, as taught by Nayar, in order to reduce processing time and thereby enhance the treatment process.

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Conclusion

7. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles Kim whose telephone number is 703-306-4038. The examiner can normally be reached on Mon thru Thurs 8:30am to 6pm and alternating Fri 9:30am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amelia Au can be reached on 703-308-6604. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ck

July 27, 2004

Jon Chang Primary Examine